

Atty. Dkt. No. 034827-3002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kevin S. Qu et al.

Title: COMPOSITIONS AND
METHODS FOR DETERMINING
GENOTYPES

Appl. No.: 10/714,508

Filing Date: 11/14/2003

Examiner: Unknown

Art Unit: 1645

<p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p><u>DIANE GARCIA</u> (Printed Name)</p> <p><u>Diane Garcia</u> (Signature)</p> <p><u>5-4-2004</u> (Date of Deposit)</p>
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INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without*

Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even

entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit
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Respectfully submitted,

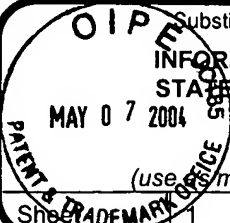
Date 5/3/04

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 Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use <u>6</u> many sheets as necessary) Sheet <u>1</u> of <u>5</u>		Complete if Known	
		Application Number	10/714,508
		Filing Date	11/14/2003
		First Named Inventor	Kevin Z. Qu
		Group Art Unit	1645
		Examiner Name	Unknown
		Attorney Docket Number	034827-3002

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	5,359,045		Soubrier et al.	10-25-1994	
	A2	6,008,373		Waggoner et al.	12-18-1999	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A3	Amant et al., "D allele of the angiotensin I-converting enzyme is a major risk factor for restenosis after coronary stenting." <i>Circulation</i> , 96:56-60 (1997)	
	A4	Beohar et al., "Angiotensin-I converting enzyme genotype DD is a risk factor for coronary artery disease." <i>J Investing Med</i> 43:275-280 (1995)	
	A5	Cambien <i>et al.</i> , "Deletion polymorphism in the gene for angiotensin-converting enzyme is a potent risk factor for myocardial infarction." <i>Nature</i> 359: 641-44 (1992).	
	A6	Canbien, "The antiotensin-converting enzyme (ACE) genetic polymorphism: its relationship with plasma ACE level and myocardial infarction." <i>Clin Genetic</i> ; 46:94-101 (1992)	
	A7	Dakik et al. "Association of angiotensin I-converting enzyme gene polymorphism with myocardial ischemia and patency of infarct-related artery in patients with acute myocardial infarction." <i>J Am Coll Cardiol</i> , 29:1468-73 (1997)	

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Sheet	2	of	5	Attorney Docket Number	034827-3002

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	A8	de Azevedo et al., "ACE and PC-1 gene polymorphisms in normoalbuminuric Type 1 diabetic patients: A 10-year prospective study." J Diabetes and Its Compl;16:255-262 ,(2002)		
	A9	Dolnik, "DNA sequencing by capillary electrophoresis (review)." J Biochem. Biophys. Meth. 41:103-19, (1999)		
	A10	Dovichi and Zhang, DNA Sequencing by capillary array electrophoresis. Meth. Mol. Biol. 167:225-39, (2001)		
	A11	Gardemann et al., "ACE I/D gene polymorphism: presence of the ACE A allele increases the risk of coronary artery disease in younger individuals." Atherosclerosis, 139:153-159 (1998)		
	A12	Grifa et al., Screening of neurofibromatosis type 1 gene : identification of a large deletion and of an intronic variant. Clin. Genet. 47: 281-84 (1995)		
	A13	Hafner et al., Isothermal amplification and multimerization of DNA by Bst DNA polymerase. Biotechniques Apr;30(4):852-6, 858, 860 passim (2001).		
	A14	Heller, Principles of DNA separation with capillary electrophoresis Electrophoresis 22:629-43, (2001)		
	A15	Higaki et al., "Deletion allele of antiotensin-converting enzyme gene increases risk of essential hypertension in Japanese men: The Suita Study." Circulation 101: 2060-65 (2000)		

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	A16	Kampke et al., Efficient primer design algorithms," <i>Bioinformatics</i> 17: 214-225 (2001)	
	A17	Kennon et al., Angiotensin-converting enzyme gene and diabetes mellitus. <i>Diabet. Med.</i> 16: 448-58 (1999)	
	A18	Kurland et al., Angiotensin converting enzyme gene polymorphism predicts blood pressure response to angiotensin II receptor type 1 antagonist treatment in hypertensive patients. <i>J. Hypertens.</i> 19: 1783-87 (2001)	
	A19	Marian et al., "Interactions between angiotensin-I converting enzyme insertion/deletion polymorphism and response of plasma lipids and coronary atherosclerosis to treatment with fluvastatin." <i>J Am Coll Cardiol</i> 35:89-95 (2000)	
	A20	McNamara et al., "Pharmacogenetic interactions between B-blocker therapy and the angiotensin-converting enzyme deletion polymorphism in patients with congestive heart disease." <i>Circulation</i> 103:1644-1648 (2001)	
	A21	Mitchelson, The application of capillary electrophoresis for DNA polymorphism analysis <i>Methods Mol. Biol.</i> 162:3-26, (2001)	
	A22	Morris and Zee, Similarity of blood pressure for each genotype of the insertion/deletion polymorphism of the dipeptidyl carboxypeptidase-1 gene in different age groups of patients with severe, familial essential hypertension." <i>Clin. Exp. Pharmacol., Physiol.</i> 21: 919-24 (1994)	
	A23	O'Malley et al., "Angiotensin-converting enzyme DD genotype and cardiovascular disease in heterozygous familial hypercholesterolemia." <i>Circulation</i> 97:1780-1783 (1998)	

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	A24	Odawara et al., Mistyping frequency of the angiotensin-converting enzyme gene polymorphism and an improved method for its avoidance. Hum. Genet. 100: 163-66 (1997)	
	A25	Okamura et al., "Pharmacogenetic analysis of the effect of angiotensin-converting enzyme inhibitor on restenosis after percutaneous transluminal coronary angioplasty." Angiology, 50:811-822 (1999)	
	A26	Okumura et al., Quinapril prevents restenosis after coronary stenting in patients with angiotensin-converting enzyme D allele. Circ. J. 66: 311-316 (2002)	
	A27	Pfohl et al., "Insertion/deletion polymorphism of the antiotensin I-converting enzyme gene is associated with coronary artery plaque calcification as assessed by intravascular ultrasound." JACC 1998; 31:987-991	
	A28	Protonotarios et al., Genotype-phenotype assessment in autosomal recessive arrhythmogenic right ventricular cardiomyopathy (Naxos Disease) caused by a deletion in plakoglobin J. Am. Coll. Cardiol. 38: 1477-84 (2001)	
	A29	Ribichini et al., Plasma activity and insertion/Deletion polymorphism of angiotensin I-converting enzyme. Circulation 97: 147-54 (1998)	
	A30	Rigat et al., PCR detection of the insertion/deletion polymorphism of the human angiotensin converting enzyme gene (DCP1) (dipeptidyl carboxypeptidase 1) Nucl. Acid Res. 20: 1433 (1992)	
	A31	Ruiz et al., "Insertion/deletion polymorphism of the angiotensin-converting enzyme gene is strongly associated with coronary heart disease in non-insulin-dependent diabetes mellitus." Proc Natl Acad Sci USA 3662-3665 (1994)	

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	A32	Saiki, "Amplification of Genomic DNA" in <i>PCR Protocols</i> , Innis et al., Eds., Academic Press, San Diego, CA 1990, pp 13-20;		
	A33	Shanmugan et al., Mistyping ACE heterozygotes. <i>PCR Methods Applications</i> 3: 120-21 (1993)		
	A34	van der Weide and Steijns, Cytochrome P450 enzyme system: genetic polymorphisms and impact on clinical pharmacology. <i>Ann. Clin. Biochem.</i> 36: 722-29 (1999)		
	A35	Wharam <i>et al.</i> , Specific detection of DNA and RNA targets using a novel isothermal nucleic acid amplification assay based on the formation of a three-way junction structure. <i>Nucleic Acids Res.</i> Jun 1;29(11):E54-E54 (2001)		
	A36	Winkelmann <i>et al.</i> , "Pharmacogenomics and Complex Cardiovascular Diseases - Clinical Studies in Candidate Genes," in <i>Pharmacogenomics</i> , Licinio and Wong, eds., pp. 251-61, Wiley-VCH, (2002)		
	A37	Zee et al., Insertion variant in intron 9, but not microsatellite in intron 2, of the insulin receptor gene is associated with essential hypertension. <i>J. Hypertens. Suppl.</i> 12: S13-S22 (1994)		

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